DOCKET NO.: JANS-0028 PATENT

Application No.: 10/019,376

Office Action Dated: March 25, 2004

REMARKS/ARGUMENTS

Claims 1, 3 to 13, and 16 to 19 are pending in this application and are rejected. Applicants are herein amending claims 1, 6, and 13.

Claim Amendments

Applicants are herein amending the claims in the following manner:

- Applicants are amending the term "a prodrug" to recite "an ester or amide prodrug" in claims 1 and 6. Support for the amendment may be found in the specification page 4, lines 29 to 34.
- Applicants are adding an "or" in the definitions of X^2 and Het in claim 1 to present the definitions of X^2 and Het in proper form.
- Applicants are substituting the terms " C_{1-4} alkylene- NR^4 , or NR^4 - C_{1-4} alkylene" for " C_{1-4} alkyl- NR^4 , NR^4 - C_{1-4} alkyl" in claim 1 to properly present them as divalent radicals for X^2 .
- Applicants are deleting use of the phrase "such as 2, 3 or 4" in claim 1.
- Applicants are adding the term "isoquinolinyl" to the definition of R¹. Support for the amendment may be found in original claim 6 and in the specification on page 10, lines 15 to 16 where (±)-N-[1-(2-amino-3-methylbutyl)-4-piperidinyl]-1-(1-isoquinolinyl methyl)-1H-benzimidazol-2-amine trihydrochloride trihydrate is preferred compound and R¹ is isoquinolinyl.
- Applicants are amending claim 6 to add a close bracket in the compound:
 - (±)-*N*-[1-(2-amino-3-methylbutyl)-4-piperidinyl]-1-(3-chloro-5,6,7,8-tetrahydro-5-quinoxalinyl)-*1H*-benzimidazol-2-amine trihydrochloride monohydrate.
- Applicants are amending claim 13 to resize and properly present the structure of compound of structural formula (I-a-1-3-1). Support for the amendment may be found on page 15, line 1.
- Applicants are amending claim 13 to add a period after the step labeled n).

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Applicants submit that the amendments to the claims do not introduce new matter and are

fully supported by the specification and claims, as originally filed.

Rejection under 35 U.S.C. § 112 (First Paragraph)

Claims 1, 3 to 9, 13 and 16 to 19 are rejected under 35 U.S.C. § 112 (first paragraph)

are allegedly not enabled because of the inclusion of prodrugs of the compounds of the

invention. Applicants are herein amending claims 1 and 6 to further specify the compounds

include the ester and amide prodrug forms thereof. As described in the specification with

reference to Gilman and Goodman's The Pharmacological Basis of Therapeutics, it is

respectfully submitted that a skilled artisan would know how to make and use ester and

amide derivatives of the compounds of formula (I) that would be hydrolyzed in vivo to form

the compounds of formula (I). Applicants submit that claims 1, 3 to 9, 13 and 16 to 19, as

amended, are enabled. Accordingly, applicants request withdrawal of the rejection of claims

1, 3 to 9, 13 and 16 to 19 under 35 U.S.C. § 112 (first paragraph).

Rejection under 35 U.S.C. § 112 (Second Paragraph)

Claims 1, 3 to 13 and 16 to 19 are rejected under 35 U.S.C. § 112 (second paragraph)

are allegedly indefinite. Applicants are herein amending claims 1, 6, and 13, as described

above in "Amendments to Claims." Applicants respectfully submit that claims 1, 3 to 13, and

16 to 19, as amended, are definite.

Applicants submit that the term "C2-5alkanediyl" in the definition of R2 is accurately

presented as a divalent moiety. Please note that "C2-5alkanediyl" is defined as an optional

substituent on the C_{1-10} alkyl substituted with $N(R^6)_2$. This implies that the divalent

" $C_{2\text{-5}}$ alkanediyl" is linked at both ends to the $C_{1\text{-10}}$ alkyl chain. As such, R^2 remains

monovalent, as required. Table 12 includes several examples, including compounds 157,

168, and 175, which exemplify the "C₂₋₅alkanediyl" on the C₁₋₁₀alkyl chain.

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Accordingly, applicants request withdrawal of claims 1, 3 to 13, and 16 to 19 under 35 U.S.C. § 112 (second paragraph).

Conclusions

Applicants request the Examiner to:

- (1) enter the amendments to the claims; and
- (2) reconsider and withdraw the rejection of claims 1, 3 to 13 and 16 to 19; and
- (3) pass claims 1, 3 to 13 and 16 to 19 to allowance.

If the Examiner is of a contrary view, the Examiner is requested to contact the undersigned attorney at (215) 557-3861.

Date: June 24, 2004

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